

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent Application:	09/965,740
Confirmation Number	4440
Attorney Docket No.	QMT1.1-CIP-US

Via EFS-Web

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

SUPPLEMENTAL RESPONSE OF DECEMBER 28, 2009

Applicants hereby submit the following Amendment to the Response of November 9, 2009 to the Examiner's Non-Final Office Action of June 9, 2009 in the above-identified matter. Applicants believe that no fee is required for this response.

AMENDED RESPONSE

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4. ADDITIONAL ARGUMENTS OF APPLICANTS

A. FURTHER SUPPORT FOR NON-OBVIOUSNESS

Under 35 U.S.C. § 103 a “patent may not be obtained if the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art...” One should also consider the inferences and creative steps that person of ordinary skill in the art would employ, *KSR International, Inc. v. Teleflex, Inc.* 550 U.S. 398, 411, 82 USPQ2d 1385, 1397 (2007). In addition, secondary considerations, such as commercial success, long felt but unsolved needs, failure of others, and industry recognition, may serve as evidence of non-obviousness, *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

Applicants assert that one of ordinary skill in the art would not have conceived of Applicant's invention as claimed. In support of the assertion, Applicants note that the FDA reviewer, who would be expected to be highly skilled in the art, rejected the opportunity to find that one embodiment of Applicants' invention did not provide. Applicants' invention provided a predictable benefit. The FDA reviewer determined that there was no substantially similar predicate device from which to make a pre-market approval determination. Instead a *de novo* review process was required. Applicants assert that the FDA reviewer's determination supports that the embodiment was not an obvious variation of prior art devices.

For further support for the non-obviousness of Applicants' invention, we point the Examiner to the following statements concerning the process that Quick-Med